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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/500,512 02/09/00 CLARK

R 001.00251

EXAMINER

HM12/0731

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ART UNIT

PAPER NUMBER

1614

DATE MAILED:

07/31/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/500,512

Applicant(s)

CLARK ET AL.

Examiner

Vickie Y. Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of application***

1. Acknowledgement is made of amendment and election filed June 25, 2001. Claims 33-34 are added. The claims 1-34 are pending.

### ***Election acknowledged***

1. Election of group I, claims 1-17 was made with traverse. Applicant's traverse is carefully considered and partially persuasive. Thus partial restriction requirement is withdrawn. Group II will be examined together with Group I however group III will be maintained as restricted. Applicant's election with traverse in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the inventions are closely related where there is no serious search burden for the examiner. This is not found persuasive because they are distinct invention where the claimed composition is used not only for enhancing migrating fibroblast in wound treatment, but also used for formatting fibrin, coagulating blood clot in the treatment of burns, plastic or reconstructive surgery, tissue grafting, or treatment of anastomotic sites, where the examiner's burden for search is extensively increased. A reference which anticipates the invention of Group I-II would not render the invention of Group III obvious, absent ancillary art, restriction for examination purposes as indicated is proper. Even if there were unity of classification, the search of entire groups and/or genus in the non-patent literature (especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made **FINAL**.

*Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-25 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pines et al (US 5,330,974) in view of *Gault* (1997)

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The claims 1-15 read on a method for enhancing fibroblast migration at a wound site comprising fibrinogen composition prepared by a process which comprises precipitating plasma with glycine in the treatment of wound. Claims 16-25 and 33-34 requires lipid rich component in the composition.

Pines teaches a therapeutically effective fibrinogen composition used as adhesive, hemostat or sealant by formatting fibrin network(see abstract). It also teaches a process of making the composition where the critical step requires precipitating fibrinogen with glycine(see column 3, line 35). Furthermore, it teaches the medical utility in wound treatment by stating that it is advantageously used in wound treatment via fibrin network formation and epithelial cells(for tissue regeneration and repair) migration (see column 1, lines 40-49). US'974 teaches other protein species(lipid rich layer) contacted by the composition such as fibronectin, factorXIII, albumin, globulin (see column 8, lines 30-45).

Applicant's claims differ because they call for fibroblast migration. However it would have been obvious to one of ordinary skill in the art to draw conclusion that fibrinogen is active

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component whereto the fibroblast is attaching when Pines is taken in view of Gailit . Gailit teaches the migration of fibroblasts into wound site via attaching to fibrinogen using intergrins. Gailit(1997) teaches that the fibroblast migration requires matrix of the fibrin clot.

One would have been motivated to use fibrinogen to enhance the fibroblast migration at the wound site because fibrinogen provides critical elements required for the migration as mentioned earlier via formatting fibrin clot or providing attachment receptors for fibroblast intergrins. Furthermore, fibrinogen with lipid rich proteins increases chemotaxis which results in enhanced fibroblast migration, and provides other additive benefits. The dependent claims are properly included in this rejection because the elements required by these claims (e.g. buffer, pH, amount of glycine) could be modified within the skilled level of artisan.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem(wound healing via enhancing fibroblast migration into wound site) which applicant is concerning. MPEP 2141.01(a).

### ***Conclusion***

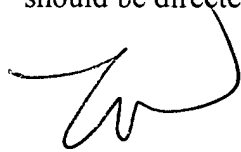
All the elected claims(1-25 and 33-34) are rejected.

Non-elected claims are withdrawn from consideration.

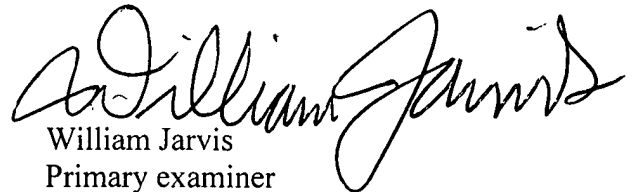
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 746-3165.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Patent examiner  
July 20, 2001



William Jarvis  
Primary examiner  
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